No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A.,
Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE* BAR ASSOCIATION OF THE DISTRICT OF COLUMBIA IN SUPPORT OF PETITIONER

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INTEREST OF THE AMICUS CURIAE

The Bar Association of the District of Columbia ("BADC") respectfully submits this brief as *amicus curiae* in support of petitioner.[1]

Founded in 1871, the BADC, a non-profit organization, is one of the oldest bar associations in the nation. The BADC and its members have a proud history of working closely with the judiciary, courts, the DC council, and the U.S. Congress on the administration of justice. The Intellectual Property Section ("IP Section") of the BADC draws its membership from individuals in government, industry, and private practice having an interest in intellectual property law including patent, trademark, and copyright law. The IP Section has a substantial interest in the adjudication of significant issues related to patent laws and submits *amicus curiae* briefs only when issues of significant importance arise. This case presents such an important issue. The Federal Circuit's interpretation of the Leahy-Smith America Invents Act ("AIA") and its failure to recognize the change that the AIA made to the on-sale bar will have an impact on many of the more than one million

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[1] This brief is presented by The Bar Association of the District of Columbia under Supreme Court Rule 37.2(a). Petitioner and Respondents have filed their blanket consent to the filing of *amicus curiae* briefs with the Court on February 28, 2018 and March 19, 2018, respectively. Counsel of record for all parties have received notice of the BADC's intent to file an *amicus curiae* brief at least 10 days prior to the due date for the *amicus curiae* brief. No counsel from either party authored any part of this brief. Only *amicus curiae* made a monetary contribution to the preparation and submission of this brief.

patentees who hold patents granted since the AIA has been in effect. It will also continue to cast a cloud of uncertainty over a countless number of patents that will be issued in the future. This Court's guidance regarding the AIA's revision is of critical importance to the entire patent community.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Federal Circuit's failure to recognize the fundamental change in on-sale bar law under the AIA[2] will have the clearly unintended and damaging consequence of discouraging innovation. This incorrect interpretation of the AIA on-sale bar discriminates against and penalizes small innovators as they compete with large companies with dedicated internal facilities. Large corporations employ a vertically integrated business model with their own in-house development and distribution facilities to carry out all of the necessary work, avoiding external development contracts that linger as hidden patent validity "landmines." Since large corporations do not need to contract with third parties to manufacture or distribute their goods, they are free to conduct preparations for distribution of a future product without concern that their actions will trigger the AIA on-sale bar.

Small companies, in comparison to their vertically-integrated competitors, operate in a much different fashion and rely heavily on outsourcing development, manufacturing, and distribution activities to third

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[2] Pub. L. No. 112-29, § 3(b), 125 Stat. 284, 285-86 (2011) (codified at 35 U.S.C. § 102(a)(1)).

parties. The Federal Circuit's application of the AIA on-sale bar to transactions where an innovator contracts with a third party distributor (who agrees to and does keep the claimed invention confidential) penalizes small companies that do not have the resources or facilities to develop and distribute their products in-house. This interpretation is inconsistent with the intent of the AIA.

The issue raised by Petitioner is of utmost importance as the number of startups and small companies is growing at a rapid rate. The business model has moved away from vertical integration and shifted to outsourcing capital-intensive functions such as manufacturing and distribution. For example, small pharmaceutical and biotechnology companies and products are becoming increasingly more common. In recent years, the majority of approved drug products originated at smaller pharmaceutical companies (64% in 2016). Outsourcing allows smaller companies to be more agile, efficient, and focused. If the Federal Circuit's decision is allowed to stand and the on-sale bar of the AIA is triggered by a patentee's outsourcing of distribution functions, companies driving innovation will be penalized. And the objectives of patent law under the Constitution—"[t]o promote the progress of science and the useful arts"—will not be met. *See* U.S. Const., art. I, § 8, cl. 8. In order to protect innovation, ensure uniformity, and carry out the mandate of the U.S. Constitution, this Court should grant Helsinn Healthcare S.A.'s ("Helsinn") petition for certiorari.

REASONS FOR GRANTING THE PETITION

I. The Federal Circuit's Decision Is Inconsistent with the Statutory Text

Not only does the Federal Circuit's decision have grave implications for small companies like Helsinn, but it also violates fundamental principles of statutory interpretation. The pre-AIA on-sale bar provided, in relevant part, that a patent could not be obtained for an invention that was "on sale in this country, more than one year prior to the date of application for patent in the United States." 35 U.S.C. § 102(b) (2006). In sharp contrast, the on-sale bar provision under the AIA provides, in relevant part, that a patent cannot be obtained if "the claimed invention was patented, described in a printed publication, or in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention." 35 U.S.C. § 102(a)(1) (emphasis added). The AIA added the phrase "or otherwise available to the public" to the statute. As described in Helsinn's petition, and as the PTO and AIA's sponsors have recognized, the AIA's text demonstrates that the phrase "otherwise available to the public" clarifies the scope of the preceding phrase "on sale." The AIA requires that a sale make an invention "available to the public."

The Federal Circuit's interpretation of the AIA on-sale bar fails to recognize that under the AIA, an offer for sale that does not make the claimed invention available to the public no longer triggers the on-sale bar. Confidential distribution arrangements relating to how an invention will be distributed in the future are not the kind of activity that make the invention available to the public. In failing to account for this

significant change in law, the Federal Circuit ignored this Court's admonition that "when Congress acts to amend a statute, [this Court] presume[s] it intends its amendment to have real and substantial effect." *Pierce Cty. v. Guillen*, 537 U.S. 129, 145 (2003) (quoting *Stone v. INS*, 514 U.S. 386, 397 (1995)). The Federal Circuit's interpretation does not give any effect to the new phrase in section 102(a)(1) ("otherwise available to the public") and therefore, it cannot be the proper construction of the statute. *Pierce*, 537 U.S. at 145 ("That reading gives the amendment no real and substantial effect and, accordingly, cannot be the proper understanding of the statute."). The "otherwise available to the public" phrase should be given its proper meaning and secret offers for sale should no longer implicate the AIA on-sale bar. The actions of Congress cannot be nullified by the Federal Circuit's decision here.

II. The Federal Circuit's Decision Will Have a Chilling Effect on Innovation

A. Small Innovators Are Important Contributors to Today's Economy

The patent laws need to protect the interests of inventors and create incentives for filing new patent applications in order to drive innovation. The benefit to the economy is not the only advantage that arises from protecting innovation: in exchange for a limited period of exclusivity, the public receives the benefit of the invention. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998) ("[a]s we have often explained . . . the patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure

of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.").

In today's economy, the corporate structure is rapidly changing. The number of startups and small pharmaceutical and biotechnology companies has greatly increased and these agile companies are making important advances in science and technology. For example, small pharmaceutical companies acquire drugs from other companies (like Helsinn did here) or academia and seek to commercialize them. *See, e.g.*, Pet. App. 79a. These companies, like Helsinn, do not typically have their own formulation research and development laboratories and rely on third parties, such as contract research organizations ("CROs") and contract manufacturing organizations ("CMOs") to accomplish their goals. *Id.* In contrast, large pharmaceutical companies are typically vertically integrated, which means that they carry out all of their work in-house. This work includes drug discovery, preclinical research, clinical development, regulatory work, manufacturing, distribution, sales, and marketing.

The small pharmaceutical and biotechnology sectors have experienced growth over the years. A recent study found that the majority of drugs approved by the U.S. Food and Drug Administration ("FDA") (64% in 2016) were developed at smaller pharmaceutical companies. Jennifer Alsever, *Big Pharma Innovation in Small Places*, FORTUNE (May 13, 2016), http://fortune.com/2016/05/13/big-pharma-biotech-startups/; *see also* J.A. DiMasi et al., *Innovation in Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECONOMICS, 20, 31 (2016) (noting the

growth of the small pharmaceutical sector). The biotechnology sector grew at a compounded annual rate of 3.7 percent between 2010 and 2016, from approximately $263 billion to a projected $293 billion. *2017 Global Life Sciences Outlook: Thriving in Today's Uncertain Market*, Deloitte, 2017. These statistics prove that small pharmaceutical and biotechnology companies are important contributors to driving innovation. As they continue to grow, the Federal Circuit's decision will continue to have the damaging consequence of discouraging innovation.

B. Concerns Regarding the AIA On-Sale Bar May Prevent Important Pharmaceutical and Biotechnology Products from Reaching the Market

1. Helsinn's Important Aloxi® Drug Product

Helsinn is a small, family-owned pharmaceutical company based in Switzerland. Pet. 8. The patent at issue here (U.S. Patent No. 8,598,219) protects Helsinn's drug product Aloxi®, which helps improve the lives of cancer patients by reducing nausea and vomiting caused by chemotherapy treatment.[3] Pet. 9-10. Bringing Aloxi® to the market was a very long and expensive process. At one point, the large pharmaceutical company (Roche) that Helsinn purchased the molecule from deemed the project too risky to pursue. Pet. 30-31. Helsinn took a risk and invested significant resources into developing the drug

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[3] Aloxi® is a pharmaceutical composition containing palonosetron hydrochloride as the active ingredient. Pet. 9.

product that is now Aloxi®. Pet. 30-31; Pet. App. 114a. The drug development process was not easy and Helsinn faced difficult challenges, such as developing a product that was stable enough that it did not degrade before it was finally given to patients suffering from the effects of chemotherapy. Pet. App. 95a-96a. Helsinn's persistence paid off and scientists found that lower concentrations of the active pharmaceutical ingredient promoted stability while still delivering a dose that was effective in combatting nausea and vomiting.

2. The Transaction at Issue Here

Helsinn, a family-owned company, did not have its own manufacturing or distribution facilities at the time it was developing its palonosetron product. *See* Pet. App. 34a, 79a. Around 1998, right before Helsinn began developing the product at issue, it had about 200-250 employees. Pet. App. 78a. Like many small companies that are not vertically integrated, it needed to outsource these capital-intensive activities to third parties. During the long and difficult drug development process, Helsinn needed to find a partner to share some of the risk it faced in developing the product. After an extensive search, it found MGI Pharma ("MGI"), a small Minnesota company. Pet. 9.

Helsinn entered into a license agreement and a distribution arrangement with MGI. *Id.* The agreements obligated MGI to make upfront payments to Helsinn if Helsinn's products received FDA approval. The distribution arrangement provided for MGI to purchase palonosetron products from Helsinn, if the products received FDA approval. *Id.* The agreements required MGI to keep proprietary knowledge relating

to the products confidential. *Id.* MGI adhered to its confidentiality obligations and in its SEC filings, redacted any information relating to the palonosetron formulations. *Id.* at 10. The details regarding the formulations were also omitted from a joint press release announced by both parties. *Id.* Information regarding the claimed invention was, therefore, not available to the public.

3. Distribution Arrangements Are Pre-Commercial Activity that Does not Trigger the On-Sale Bar of the AIA

Distribution agreements constitute pre-commercial planning activities and should not trigger the on-sale bar of the AIA. They merely set up a framework for distribution of a product if and when it is approved. They do not make the invention available to the public. Here, Helsinn had not obtained FDA approval for its product at the time it entered into the agreement with MGI. Moreover, there was no guarantee that the FDA would approve Aloxi® at the time of contracting. Since Helsinn did not have its own in-house manufacturing and distribution facilities, it had to outsource these functions to third parties. It needed a plan in place so that it would have the resources to bring the drug to hospitals and patients in the future, if it did receive FDA approval. Neither Helsinn nor MGI could have sold the product to anyone because the FDA had not issued its approval at the time the parties entered into the agreement. The transaction at issue in Helsinn constituted pre-commercial activity that was done to prepare for later commercialization of the product (after it was approved by the FDA). *See In re Kollar*, 286 F.3d 1326, 1334 (Fed. Cir. 2002) (holding that

"[t]he pre-commercialization process aimed at making the invention commercial" does not implicate the on-sale bar).

Judge O'Malley acknowledged that "[i]t is fair to question whether * * * distribution agreements *should* fall within the scope of the on-sale bar . . . ." Pet. App. 15a (O'Malley, J., concurring in the denial of panel rehearing) (emphasis in original). She described that the purpose of entering into distribution agreements is to "mak[e] preparations to sell products to the public in the *future*" and noted that "these agreements do not themselves effectuate consummated sales to end users." *Id.* (emphasis in original). Concerns regarding application of the on-sale bar based on the patentee's preparation and planning activities predate the AIA:

> The on-sale bar's applicability to commercial agreements entered into for the purpose of preparing to make future sales has provoked criticism long before Helsinn. *Cf. McCreery Eng'g Co. v. Mass. Fan Co.*, 195 F. 498, 502 (1st Cir. 1912) (noting that "there is reason to doubt whether an offer to deliver an article at a future time is in substance a putting on sale before the time of actual delivery").

Pet. App. 16a. Judge Reyna voiced concerns for small companies that need to outsource in his dissent in *Hamilton Beach Brands*, which arose under the pre-AIA on-sale bar: "My greatest concerns involve the implications this case will have for future innovators, most notably small enterprises and individual inventors who lack in-house prototyping and fabricating capabilities." *Hamilton Beach Brands, Inc.*

v. Sunbeam Prods., 726 F.3d 1370, 1381 (Fed. Cir. 2013) (Reyna, J., dissenting).

If small pharmaceutical and biotechnology companies face the risk that their contractual distribution agreements with third parties may years later trigger the AIA on-sale bar, it could prevent them from bringing new products to the public. Many drugs—including Aloxi®—are discovered by small pharmaceutical companies. Small companies frequently need the assistance of third parties to develop and distribute their products. Furthermore, many small companies, such as Helsinn, need to work with a third party to obtain funding to develop their products or face the risk of running out of money to complete the project. As Judge O'Malley recognized: "there is often a need to make distribution agreements public to induce investors to supply funding for product development." Pet. App. 15a. Moreover, small pharmaceutical and biotechnology companies may not be able to recoup their research and development investment if prior distribution arrangements are later found to invalidate patents that cover important products. The mounting expenses could cause these small companies to face dissolution or bankruptcy.

As the number of small innovator companies grows, their ability to work with third parties without fear of running afoul of the on-sale bar becomes increasingly important. If the scope of the AIA on-sale bar is not clear, small companies may not invest in risky projects that could provide life changing or life saving products. In order to promote innovation and protect the interests of all inventors (including small ones), this

Court should grant Helsinn's petition for a writ for certiorari.

III. The Federal Circuit's Decision Results in the Inconsistent Application of the AIA On-Sale Bar

While a vertically integrated corporation can make preparations for development and distribution of a product in-house without concern that these activities would invoke the AIA's on-sale bar, a small company (such as Helsinn) cannot. The different results—from application of the same statute—cannot be reconciled.

A. Small Corporations Without In-House Distribution Facilities Will Be Disadvantaged if This Court Does Not Intercede

With the business structure shifting away from vertical integration (*see supra*), outsourcing will become a mandatory part of doing business. In order to survive and compete, small companies will need to rely heavily on a number of third party providers. CROs and CMOs will help them with their research and development projects. They will also need third party distributors and outside investors. By simply contracting with a distributor prior to the critical date, a patentee could trigger the AIA on-sale bar and years later lose the patent protecting its valuable invention.

Large corporations, however, do not have to hire third parties to help with development and distribution. They have these resources in-house and can rely on their own warehouses and distribution channels throughout the country. Vertically integrated companies do not need to contract with distributors

and therefore do not typically engage in activities resulting in an offer for sale of the claimed invention.

The Federal Circuit's decision penalizes small pharmaceutical companies for outsourcing and places them in the difficult position of losing their patent rights or creating their own in-house distribution facilities. Doing so would greatly increase costs and divert economic resources away from developing important new drug products. Amy V. Beekman and Richard B. Robinson, *Supplier Partnerships and the Small, High-Growth Firm: Selecting for Success*, 42(1) J. SMALL BUSINESS MANAGEMENT, 59, 72 (2004) ("longer-term [supplier] relationships offer significant benefits and [] these benefits are enduring . . . In the sample, 86 percent of the 91 [pharmaceutical] firms had sales that grew 15 percent or greater every year during a three-year period . . . ."). Furthermore, the costs to bring new drugs to market are approximately $2.6-2.8 billion dollars. J.A. DiMasi, 47 J. HEALTH ECONOMICS at 31 (the cost is approximately $2.8 billion when estimated R&D costs incurred after initial approval are added); Jerry Avorn, *The $2.6 Billion Pill—Methodologic and Policy Considerations*, 372(20) NEW ENG. J. MED. 1877, 1877 (2015). Since these costs do not vary significantly between large and small pharmaceutical companies, saving costs becomes of great importance to the small innovators. *See* DiMasi, 47 J. HEALTH ECONOMICS at 29.

To ensure that a contractual relationship with a third-party distributer would not trigger the on-sale bar of the AIA, small companies would have to file patent applications within one year of entering such an agreement. While at first glance this does not seem too

difficult, it ignores the impracticality, expense, and burden this would place on small innovators. First, patent applications for all projects—whether or not they are successful—will have to be filed. Potential new products fail to reach the market for a number of reasons, including lack of commercial viability and failure to achieve the desired results.

Second, requiring small companies to file patent applications on all proposed inventions could cost a great deal of money. Justice Breyer noted in *Halo Electronics v. Pulse Electronics* that costs like these can prevent an innovator from getting a small business up and running. *See infra*. Moreover, this added burden is inconsistent with the business model of small companies as they strive to reduce costs and operate efficiently. Filing patent applications on projects that do not even end up being successful will waste the precious resources of small businesses. Drug products, like Aloxi®, that improve the quality of life of cancer patients, may not be able to make it to the market. The general public will be harmed and will miss out on important products that not only save lives, but improve the quality of life, often on a daily basis.

B. This Court Should Construe the AIA On-Sale Bar to Maintain a Consistent and Uniform Application

The on-sale bar of the AIA should be construed in a way that ensures a uniform application. Small companies should not be penalized and face additional burdens that do not affect vertically integrated companies. In a recent patent case, this Court considered the harm to small innovators in construing Section 284 of the Patent Act. *Halo Elecs., Inc. v. Pulse*

Elecs., Inc., 136 S. Ct. 1923 (2016). In *Halo Electronics*, Justice Breyer agreed with the majority and filed a concurring opinion to express his understanding of the limits imposed on Section 284 that "help produce uniformity in its application and maintain its consistency with the basic objectives of patent law." *Id.* at 1936. Justice Breyer considered the interests of small businesses and innovators in agreeing with the majority's interpretation of Section 284:

> The Court does not weaken this rule through its interpretation of §284. Nor should it. It may well be expensive to obtain an opinion of counsel. See Brief for Public Knowledge et al. as Amici Curiae 9 ("[O]pinion[s] [of counsel] could easily cost up to $100,000 per patent"); Brief for Internet Companies as Amici Curiae 13 (such opinions cost "tens of thousands of dollars"). *Such costs can prevent an innovator from getting a small business up and running.*

Id. (emphasis added). Justice Breyer recognized the harm that could result from requiring small businesses to obtain an opinion of counsel. The resources and expense required to do so could discourage innovation and prevent a small business from getting off the ground. The harm would occur absent this Court's intervention. Inconsistent application of the AIA's on-sale bar could discourage lawful innovation and place additional monetary burdens on small innovators who are trying to get small companies up and running.

* * *

The on-sale bar of the AIA should be construed in a way that produces uniformity in its application and avoids inconsistent results. This Court should grant certiorari here to prevent the Federal Circuit's misinterpretation of the AIA from discouraging innovation and preventing important innovations from reaching the market.

CONCLUSION

For the foregoing reasons, amicus curiae urges the Court to grant Helsinn's petition for a writ of certiorari.

Respectfully submitted,

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